

EXHIBIT E

Role of Vaginal Mesh Hysteropexy for the Management of Advanced Uterovaginal Prolapse

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OBJECTIVE: To determine the role of vaginal mesh hysteropexy in the management of advanced genital organ prolapse as assessed by subjective and objective parameters.

STUDY DESIGN: Retrospective case series of 77 women followed for at least 1 year after vaginal mesh hysteropexy performed for stage III or greater uterovaginal prolapse. The primary outcome was Pelvic Organ Prolapse Quantification (POP-Q) stage <II and no subjective bothersome bulge and no further interventions for prolapse. Secondary outcomes assessed were complications such as intraoperative bleeding, injuries, and postoperative complications such as mesh exposure, mesh retraction, dyspareunia, urinary incontinence, and voiding dysfunction.

RESULTS: Mean follow-up was 13.7 ± 4.1 months. Our composite success score was 85.7%. The anatomic (POP-Q) success score was 90.9%. Most failures (all but 1) were stage II with cervix as leading edge. Incidence of de novo dyspareunia was 3.7% and vaginal mesh erosion was 6.5%. Most patients 68/77 (88.3%) were discharged home voiding normally.

CONCLUSION: Vaginal mesh hysteropexy offers good

success; however, comparative studies are required to validate its true role. (J Reprod Med 2014;59:371–378)

...the current medical literature is inadequate to assist physicians in determining which patients with prolapse are ideal candidates for uterine preservation...

Keywords: gynecologic surgery, hysterectomy, hysteropexy, pelvic organ prolapse, uterine preservation, uterine prolapse, vaginal mesh surgery, vaginal vault prolapse.

Pelvic organ prolapse affects over half of women

over the age of 50 years and is the leading indication for hysterectomy in this age group.^{1,2} In 1997 over \$1 billion was spent on prolapse surgery in the United States, and hysterectomy accounted for over 60% of these surgeries.³ Despite this high prevalence of hysterectomy for prolapse, there have been questions raised regarding its true role in prolapse management. In fact, up to 40% of women undergoing hysterectomy subsequently present with vaginal vault prolapse.^{4,5} Also, a hysterectomy performed at the time of prolapse surgery has not been proven to improve the durability of the repair and may in fact increase morbidity, blood loss, and intraoperative and postoperative recovery times.

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Moreover, women may also be at increased risk for new onset urinary incontinence, bladder dysfunction, or prolapse following hysterectomy.^{6,7} For some women, removal of the uterus negatively influences sexual and personal identity.⁸ Additionally, concurrent hysterectomy at the time of vaginal mesh surgery increases the risk of mesh exposure fivefold.⁹

The typical etiology of uterine prolapse is loss of integrity of the uterosacral cardinal ligament complex and weakening of the pelvic muscles, allowing uterine descent below the levator plate. Hysterectomy alone fails to address this problem.¹⁰ Women are increasingly choosing to avoid hysterectomy, and some of the reasons for this are the belief that the uterus plays a role in sexual function and awareness of complications related to hysterectomy.

The idea of preserving the uterus at prolapse surgery has been entertained for several decades. In 1934 Bonney¹¹ stressed that the uterus plays a passive role in uterovaginal prolapse. In 1888 Archibald Donald of Manchester, U.K., first described the Manchester procedure as an alternative to vaginal hysterectomy for the management of uterovaginal prolapse.¹² Several surgical techniques have now been performed for the management of uterovaginal prolapse with uterine preservation. Some of these are the vaginal shortening of the cardinal ligaments with cervical amputation (Manchester procedure),¹³ uterosacral plication without cervical amputation,¹⁴ sacral promontory hysteropexy,¹⁵ Shirodkar sling hysteropexy procedure with psoas loop,¹⁶ and the sacrospinous hysteropexy.¹⁷ Some of these procedures require cervical amputation, abdominal approach, and possibly have higher risks of recurrence, especially with larger prolapses.¹⁸

The primary aim of our study was to determine the role of Prolift+M (Ethicon Inc., Somerville, New Jersey) vaginal mesh hysteropexy surgery in correcting advanced uterovaginal prolapse as assessed by subjective and objective criteria at least 1 year after surgery. The secondary objectives were to assess bowel, bladder, and sexual function following surgery and also complications following this vaginal mesh reconstruction. Prolift+M is a 50-50 blend mesh that consists of poliglecaprone 25 knitted with polypropylene. The poliglecaprone 25 (Monocryl, Ethicon, Somerville, New Jersey) is absorbed after 3 months, leaving a lower burden of mesh in the vagina, decreasing from 57 g/m² to 31 g/m² (data on file: Ethicon Inc.). The pore size following absorption increases from 2.5 mm to 3.5

mm. Preclinical studies have reported that the greater distance between pores resists the ability of "bridging fibrosis," thereby leading to a compliant and flexible scar tissue that mimics natural tissue mobility.¹⁹

Materials and Methods

This is a retrospective review of patients with advanced uterovaginal prolapse who underwent a vaginal mesh hysteropexy procedure at our center. The study was approved by the Institutional Review Board of Wayne State University. The inclusion criteria were subjects who underwent a Prolift+M mesh hysteropexy surgery for complaints of stage III or greater uterovaginal prolapse between October 2008 and February 2011. The exclusion criteria included patients who did not complete the validated questionnaires or who did not follow up for their 12-month visit.

Success was defined as Pelvic Organ Prolapse Quantification system (POP-Q) stage <II and patient satisfaction from surgery based upon Pelvic Floor Distress Inventory-20 (PFDI-20) question #3 "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" answered "No" or, if "Yes," "Not at all bothersome" and no additional interventions done for prolapse, namely pessary or surgery.

Secondary outcomes assessed were complications such as intraoperative bleeding, injuries, and postoperative complications such as mesh exposure, mesh retraction, dyspareunia, urinary incontinence, and voiding dysfunction.

All subjects underwent a detailed urogynecologic history and examination including a POP-Q assessment prior to the surgery. Patients with anterior vaginal wall prolapse underwent urodynamics with the bulge manually reduced with sponge sticks to assess for occult incontinence. All patients underwent a standardized trocar-guided transvaginal Prolift+M mesh procedure. The surgical procedure was as outlined by the manufacturer (Ethicon). The standard Total Prolift+M vaginal mesh procedure in our practice involved dividing the total mesh piece into two (the anterior and the posterior mesh) and suturing it to the cervix with 2/0 prolene sutures. The anterior mesh piece is attached to the anterior cervical stroma after dissecting the bladder cephalad, whereas the posterior part of the mesh is anchored to the posterior aspect of the cervix. One or two sutures are used for this purpose.

All subjects completed validated questionnaires at the preoperative and 12-month visits. The PFDI-20 was used as a symptom-specific questionnaire for pelvic organ prolapse. The Urogenital Distress Inventory (UDI-6) and the Medical Epidemiologic and Social aspects of Aging (MESA) forms were used to assess the degree to which symptoms associated with urinary incontinence were bothersome. The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) was used to assess pain during intercourse.²⁰ Scores of the PFDI-20 were calculated in a simple additive fashion, where a higher score indicates more distressful symptoms.²¹

For the secondary outcome, bothersome de novo incontinence was defined as a new onset incontinence that required intervention. The Dindo classification was used to assess complications.²²

All definitions and descriptions conformed to the standards recommended by the international continence society.²³ The anatomical outcome was assessed with the POP-Q score,²³ which is described by the International Continence Society as a reliable and specific method to measure the pelvic organ support.

Ethicon Inc., the manufacturer of the PP-PG mesh, had no influence over the study design, execution

of the study, interpretation of the results, and creation of the manuscript. This study was unfunded.

Data on patient and surgical characteristics are presented as frequency (%). Results from the MESA and PFDI-20 questionnaires are presented as calculated scores and frequencies. Comparisons between baseline and 12-month assessments were performed using paired sample *t* test for both POP-Q and questionnaire data. All analyses were performed using Statistical Package for the Social Sciences Version 20 (SPSS Inc., Chicago, Illinois) software.

Results

Vaginal mesh hysteropexy was performed in 77 patients who met the inclusion criteria from the time period November 6, 2008, to February 23, 2011. The mean follow-up was 13.7 ± 4.1 (range, 10–31) months. Cystourethroscopy was systematically performed in all patients undergoing a total or an anterior mesh hysteropexy. A total of 57/77 (74%) underwent surgery for POP-Q stage III and 20/77 (26%) for stage IV prolapse. The absolute uterine (C value) prolapse stage is depicted in Figure 1. Total mesh procedure was performed in 74 (96.1%) patients, 2 (2.6%) patients underwent a posterior

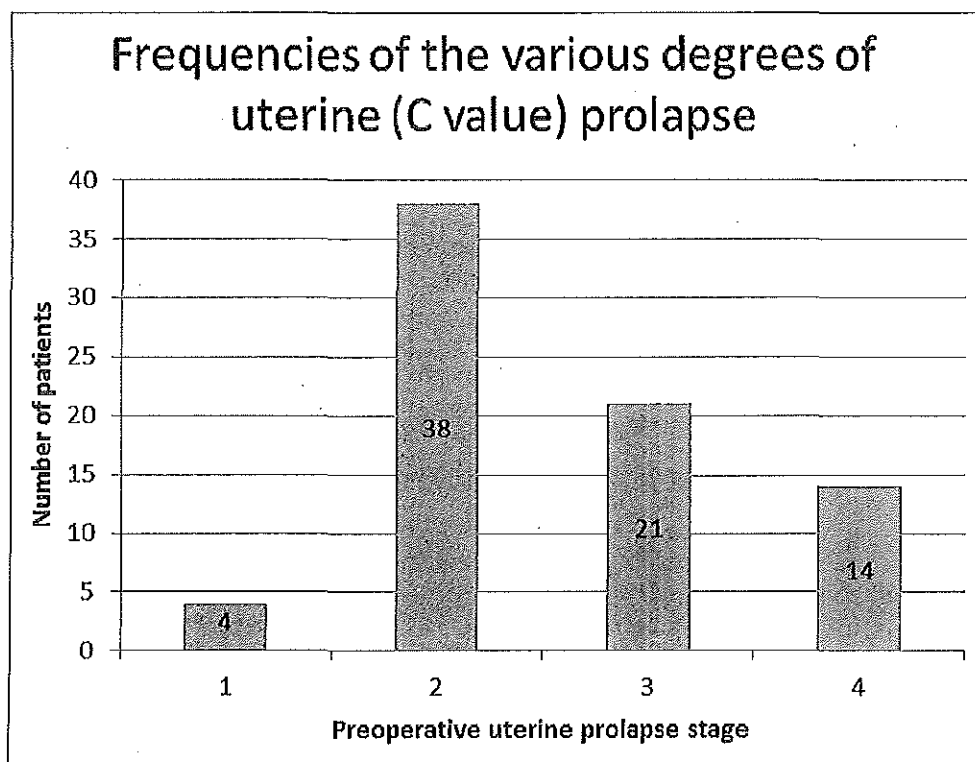


Figure 1
Frequencies of the various degrees of uterine prolapse.

mesh procedure, and 1 (1.3%) underwent an anterior mesh procedure. Concomitant sling procedure was performed in 52 (67.5%) patients, and 12 (15.6%) underwent concomitant anal sphincter repair. The demographic and surgical information is presented in Table I.

There were 11/77 (14.29%) failures as per our composite score. Three out of 11 failures had preoperative stage IV prolapse, and the remaining 8 patients had preoperative stage III prolapse. Considering just the anatomic failures, postoperative POP-Q stage II or greater was noted in 7 (9.1%) patients. Of those 7 patients, 2 were bothered by the bulge.

The change from the median preoperative C value (+1) to the median postoperative C value (-6) was statistically significant, as was the change from the median preoperative POP-Q (stage III) to the median postoperative POP-Q (stage 0), as shown in Tables II and III.

The PFDI question #3 "Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?" answered "Yes" was noted in 6 subjects (7.8%). Three subjects were "somewhat" bothered by the bulge and 3 were "moderately" bothered by it.

All patients who had intraoperative cystoscopies demonstrated normal findings without any injury. The mean blood loss was 139.21 mL (SD \pm 121.89), and none of the patients received blood transfusions. Most patients were discharged home after an overnight stay (days in hospital, 1.23 ± 0.51). Nor-

mal voiding function at discharge was noted in 67 (87%) patients. The remaining 10 patients were sent home with a Foley catheter, which was successfully removed in 9 patients at the first attempt in the office on the 7th postoperative day as per our protocol. The remaining patient failed the first attempt but was successfully voiding at the second attempt in 5 days and thereafter. Of the 10 patients who were sent home with a catheter, 7 also underwent a concomitant suburethral sling procedure.

Mesh exposure was noted in 5 (6.5%) patients, but only 1 patient needed revision of the exposure, and this was done in the office. The remaining patients were managed expectantly as the vaginal mesh exposure was asymptomatic. There were no mesh erosions in the bladder or the bowel. Two (2.6%) patients had recurrent urinary tract infections (UTIs) and were treated with antibiotics. De novo stress incontinence was noted in 3 (3.9%) patients. Two were treated with transurethral bulking procedure in the office, and the other one underwent a sling procedure 8 months postoperatively. There were 7 women who developed de novo urge per the MESA questionnaire, but none of them needed any interventions. The incidence of preoperative dyspareunia was 50% (11/22), and that of postoperative dyspareunia was 48% (13/27). The incidence of de novo dyspareunia, however, was 3.7% (1/27).

The Dindo classification is as follows: Grade I, 6 patients (1 de novo dyspareunia, 5 with mesh exposure); Grade II, 3 patients (2 UTIs, 1 straight

Table I Patient and Surgical Characteristics

Characteristic	Total (N=74)	Posterior (N=2)	Anterior (N=1)	All (N=77)
Age ^a	67.04 \pm 11.62 (34-89)	64.5 \pm 9.2 (58-71)	74 \pm 0	67.0 \pm 11.54 (34-89)
Parity ^a	2.99 \pm 1.44 (0-7)	2.5 \pm 0.7 (2-3)	3 \pm 0	2.97 \pm 1.41 (0-7)
BMI ^a	28.24 \pm 4.86 (20.3-45.7)	32.0 \pm 10.0 (24.9-39.1)	23.2 \pm 0	28.27 \pm 4.9 (20.3-45.7)
Previous prolapse surgery ^b	1 (1.35%)	0	1 (100%)	2 (2.6%)
Operating time (min) ^a	149.41 \pm 31.26 (60-243)	67.5 \pm 31.8 (45-90)	90 \pm 0	146.51 \pm 34.15 (45-243)
Blood loss (mL) ^a	143.70 \pm 122.27 (20-500)	20 \pm 0 (20)	50 \pm 0	139.21 \pm 121.89 (20-500)
Anesthesia ^b				
Spinal	71 (95.95%)	2 (100%)	1 (100%)	74 (96.1%)
General	2 (2.70%)	0	0	2 (2.6%)
Spinal and general	1 (1.35%)	0	0	1 (1.3%)
Concomitant surgery ^b				
TVT-O sling	52 (70.27%)	0	0	52 (67.5%)
Anal sphincteroplasty	12 (16.22%)	0	0	12 (15.6%)
Hospital stay (days) ^a	1.24 \pm 0.52 (1-4)	1 \pm 0	1 \pm 0	1.23 \pm 0.51 (1-4)
Intraoperative complications ^b	0	0	0	0
Mesh exposure ^b	5 (6.5%)	0	0	5 (6.5%)

^aMean \pm SD (range).

^bNumber of patients (%).

Table II Preoperative and Postoperative POP-Q Stages

POP-Q stage	Total (N=74)		Posterior (N=2)		Anterior (N=1)		All (N=77)	
	Preop	Postop	Preop	Postop	Preop	Postop	Preop	Postop
0	0	44	0	1	0	1	0	46
I	0	23	0	1	0	0	0	24
II	0	7	0	0	0	0	0	7
III	55	0	2	0	0	0	57	0
IV	19	0	0	0	1	0	20	0

catheterization for 1 week); Grade IIIa, 2 patients (mesh revision in office, transurethral bulking); and Grade IIIb, 2 patients (suburethral sling). There were no Dindo Grade IV/V complications.

Discussion

This is a retrospective study done to assess the role of vaginal mesh hysteropexy using the Prolift+M system in patients with at least stage III uterovaginal prolapse. Patients were considered to be failures if there was stage II or worse uterine prolapse or they complained of a perceptible vaginal bulge or if they required additional intervention. Our composite success score was 85.7%. The anatomic success, postoperative POP-Q stage \leq II, was noted in 90.9% of patients.

There have been several studies done on non-mesh vaginal hysteropexy for uterine preservation.²⁴⁻³⁰ Anatomic success rates in those studies varied between 74% and 93.5%, which is comparable with our results. However, when specifically looking at advanced prolapse cases, the results are inferior. In a randomized trial the recurrence rate of the apical compartment after the sacrospinous non-mesh hysteropexy at 1-year follow-up was 27%.³¹ They found that *all* subjects with a preoperative prolapse stage IV had recurrent apical prolapse after a sacrospinous hysteropexy. Lin et al reported a recurrence rate of 75% for stage III or IV prolapse.¹⁸ Based on their data they advise against performing a sacrospinous non-mesh hysteropexy in case of a stage III or IV uterine descent. In our

Table III Objective Outcomes of Vaginal Mesh Hysteropexy: Distribution of Median POP-Q Values Preoperatively and Postoperatively

Stage	Total repair (N=74)		Posterior repair (N=2)		Anterior repair (N=1)		All subjects (N=77)		p Value
	Preop	Postop	Preop	Postop	Preop	Postop	Preop III (II to IV)	Postop 0 (0 to II)	
Aa	3 (0 to 3)	-3 (-3 to -1)	0 (0 to 0)	-2.50 (-3 to -2)	3 (3 to 3)	-3 (-3 to -3)	3 (0 to 3)	-3 (-3 to -1)	0.000
Ba	3.75 (1 to 7)	-3 (-3 to -1)	1.5 (1 to 2)	-2.5 (-3 to -2)	5 (5 to 5)	-3 (-3 to -3)	3.5 (1 to 7)	-3 (-3 to -1)	0.000
C	1 (-2 to 10)	-6 (-7 to 0)	4 (3 to 5)	-5 (-6 to -4)	5 (5 to 5)	-6 (-6 to -6)	1 (-2 to 10)	-6 (-7 to 0)	0.000
D	-4 (-5 to 8)	-8 (-9 to 0)	1.5 (-1 to 4)	-7.5 (-8 to -7)	3 (3 to 3)	-7 (-7 to -7)	-3 (-5 to 8)	-8 (-9 to 0)	0.000
Ap	0 (-3 to 3)	-3 (-3 to -2)	0 (0 to 0)	-3 (-3 to -3)	-3 (-3 to -3)	-3 (-3 to -3)	0 (-3 to 3)	-3 (-3 to -2)	0.000
Bp	0 (-2 to 7)	-3 (-3 to -2)	0 (0 to 0)	-3 (-3 to -3)	-1 (-1 to -1)	-3 (-3 to -3)	0 (-2 to 7)	-3 (-3 to -2)	0.000
GH	5 (3 to 8)	4 (3 to 5)	5.5 (5 to 6)	3.5 (3 to 4)	5 (5 to 5)	7 (7 to 7)	5 (3 to 8)	4 (3 to 7)	
PB	3 (2 to 5)	3 (2 to 4)	3.25 (2.5 to 4)	3 (3 to 3)	2 (2 to 2)	3 (3 to 3)	3 (2 to 5)	3 (2 to 4)	
TVL	8 (7 to 10)	8 (5 to 9)	9 (7 to 11)	7.5 (7 to 8)	8 (8 to 8)	8 (8 to 8)	8 (7 to 11)	8 (5 to 9)	

Table IV PFDI-20 Subcategories: Preoperative Versus Postoperative

	POPDI			CRADI			UDI-6			PFDI summary		
	Preop	Postop	p Value	Preop	Postop	p Value	Preop	Postop	p Value	Preop	Postop	p Value
Average \pm	46.71 \pm	8.28 \pm		23.02 \pm	11.59 \pm		41.97 \pm	13.21 \pm		112.34 \pm	33.09 \pm	
SD	28.4	12.5	0.000	20.72	12.16	0.000	28.01	15.2	0.000	61.12	31.03	0.000
Range	8.33–100	0–50		0–89.29	0–46.88		0–100	0–79.17		8.33– 281.25	0– 163.54	

POPDI = pelvic organ prolapse distress inventory, CRADI = colorectal anal distress inventory.

study, with an overall success score of 85.7%, more patients with larger prolapse (stage IV) were successes than were failures. There was 1 patient who had a C-value of +10 with a postoperative C-value of –6. Moreover, even in patients who were failures, the cervix was still higher as compared to that preoperatively (postoperative C value –1 vs. preoperative C value +4.4).

Some studies⁶ have indicated that pelvic organ prolapse and urogenital symptoms may be only slightly correlated to the site and severity of the prolapse. However, in our study the vaginal mesh hysteropexy procedure showed good functional outcome in terms of bladder and bowel function as determined by the PFDI-20 (Table IV) and the MESA scores. In fact, there was improvement noted in both the urge and stress subscores of the MESA (Table V).

Though the incidence of de novo dyspareunia was 3.7%, only 27 subjects postoperatively and 22 preoperatively were sexually active. Although those are small numbers, it could indicate that hysteropexy may avoid the deep dyspareunia that may result from scarring and tethering at the vaginal vault following a hysterectomy.^{32,33} Moreover, the role of the cervix during sexual intercourse also could be beneficial.³⁴

The strengths of this study are the sample size, at least 1 year of follow-up, the use a standard mesh kit, a single center evaluation, and the use of both subjective and objective validated criteria to assess success. The limitation of this study is that inherent to a retrospective design, especially selection bias. Moreover, the POP-Q measurements were done by the investigators, and this too could introduce bias. This is just a short-term (1 year) study, and longer-term results are awaited, especially since some recurrences may possibly happen beyond the 1-year period.

Even though the Prolift+M mesh system is no longer available, this data still has pertinence as the

tensile strength, pore size, material type (Type IA polypropylene), and weight are similar to the other vaginal mesh systems still available today.

Uterine preservation has several advantages, such as decreased risk of dyspareunia,³⁵ mesh exposure,⁹ and urinary incontinence.²⁵ Moreover, it eliminates the inherent surgical risks of a hysterectomy. The main drawback of preserving the uterus is the need for future intervention for new cervical/uterine pathology, mainly cancer. Thus, proper preoperative counseling and assessment of the patient's gynecologic and family history is important.

The need for a hysterectomy has been questioned over decades. Shaw³⁶ in 1933 questioned it by stating, "Hysterectomy as a cure for prolapse is useless and the very worst type of prolapse is the one that occurs after hysterectomy has been performed. . . ." A recently published paper that looked at the patient's perspective on hysterectomy concluded that if offered a procedure of similar success, more women are likely to keep their uterus than undergo a hysterectomy.³⁷

Although there is a growing body of evidence supporting the concept of uterine preservation at the time of uterovaginal prolapse surgery, the current medical literature is inadequate to assist physicians in determining which patients with prolapse are ideal candidates for uterine preservation and in selecting the ideal uterus-sparing procedure for a given patient. At present, the decision is usually

Table V Preoperative and Postoperative MESA Urge and Stress Score Comparison

	Preoperative versus postoperative		p Value
	Preoperative mean	12-month postop mean	
MESA stress	7.4 \pm 7.3	3.8 \pm 4.6	0.000
MESA urge	3.9 \pm 3.7	2.32 \pm 3.1	0.003

influenced by the patient's preference and the surgeon's skill and experience. Laparoscopic hysteropexy is less well-studied, and with short-term results.¹² Two short studies have reported adequate success with abdominal hysteropexy with mesh.^{38,39} The advantages of the vaginal route over the laparoscopic/abdominal route are obvious; and although this paper is promising in its findings for vaginal mesh hysteropexy done for advanced prolapse cases, the concept needs further evaluation.

Our study allows us to generate a hypothesis that can now be tested in a prospective manner or through a randomized clinical trial to evaluate and compare the outcomes of vaginal mesh hysteropexy with traditional procedures such as vaginal hysterectomy with sacrospinous ligament suspension in terms of anatomic success, symptomatic cure, and functional outcomes. Such studies are necessary before uterine preservation can routinely be recommended at the time of uterovaginal prolapse surgery.

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